Project Proposal

For more information or guidance please see the host requirements, project examples and project characteristics as found on the NDSR website.

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Date Submitted

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Submitted by:

[redacted]

Project Proposal Title

Enabling Open Science through the Center for Devices & Radiological Health (CDRH) Science Data Ca

Project Summary
(provide 2-3 sentences summarizing the project)

The FDA Center for Devices & Radiological Health (CDRH) Science Data Catalog is a pilot project to build a searchable discovery tool of public CDRH datasets, software code, computational models, and radiological images. This Catalog will provide seamless, enduring access to the diversity of CDRH-generated research outputs across a variety of science and engineering disciplines. The resident will assist in advancing open science and strengthening the regulatory pipeline by enabling data sharing, reproducibility, and reuse.

Specific Goals and Objectives
(identify goals and objectives to be completed by end of residency)

-Support the planning and delivery of a Minimal Viable Product of the CDRH Science Data Catalog by participating in all aspects of catalogue design and development.
-Lead inventory of public Office of Science & Engineering Laboratories (OSEL) research data, including datasets, software code, computational models, radiological images, etc.
-Assist with the development and refinement of custom descriptive metadata elements such as: device area, body system, patient population, disease state, product code, regulatory review, etc.
-Plan and manage a 4-6 Division pilot with OSEL/CDRH research staff.
-Lead the curation of test content for pilot from selected OSEL research programs, such as: Division of Biomedical Physics; Division of Applied Mathematics; Division of Biology, Chemistry, and Material Science; or Division of Imaging, Diagnostics & Software Reliability.
-Develop a business model for management and maintenance of the CDRH Science Data Catalog, including: administrative policies, workflows, and processes.
-Collaborate with the CDRH Public Access Working Group, FDA Public Access Steering Committee, and FDA Data Management Working Group to ensure strategic alignment with broader efforts.
-Partner with FDA.gov, OpenFDA, and Data.gov to engage the public with marketing and outreach.

Timeframe and Deliverables

(provide a quarterly breakdown of assignments and deliverables necessary to complete objectives)

QUARTER 1:
- Participate in the FDA working group that is guiding implementation of the agency's public access policy (ongoing activity).
- Perform project planning, to include creating a project charter, project plan, and timeline.
- Research existing data catalog implementations in federal government.
- Gather requirements and conduct stakeholder interviews for the CDRH Science Data Catalog.
- Research potential software solutions for the Data Catalog.
- Map out the business process workflows for the Data Catalog.
- Develop a project communication plan.

QUARTER 2:
- Complete a content inventory to determine the amount, types, and locations of CDRH digital data.
- Develop the metadata schema for the Data Catalog.
- Select software for the implementation of the Data Catalog.
- Revise the business process workflows for the Data Catalog, if necessary (ongoing activity).

Resources Required

(identify any resources necessary to complete the project)

Two mentors [redacted]. One resident.

The Office of Science and Engineering Laboratories will provide a workspace at FDA's White Oak campus in Silver Spring. The resident will be in a collaborative open office, co-located with one mentor and the Innovation and Technology Solutions Team.

CDRH will provide software and hardware needed to undertake the work for this project. Access will be provided to CDRH staff in order to gather requirements and obtain stakeholder feedback. The resident will cooperate with open data implementers in FDA's Office of the Chief Scientist and in other FDA centers as needed.

Context

(provide a narrative statement explaining the project – no more than 500 words)

In February 2013, the White House Office of Science and Technology Policy (OSTP) issued a memorandum to the heads of executive departments and agencies entitled "Increasing Access to the In February 2013, the White House Office of Science and Technology Policy (OSTP) issued a memorandum to the heads of executive departments and agencies entitled "Increasing Access to the Results of Federally Funded Scientific Research." To increase public access to the results of research funded by the Federal Government, OSTP directed federal agencies such as the FDA to provide free public access to federally funded, peer-reviewed, scientific publications and their associated data. The OSTP memo also directed agencies to maximize public access, to the extent feasible and permitted by law, to digitally formatted data resulting from federally funded research.

In December 2015, FDA published its final Policy on Public Access to Results of FDA-Funded Scientific Research. The policy states that FDA intramural researchers must submit data management plans for their digital data and provide public access to research data as provided in their approved data management plans.

The creation of a CDRH Science Data Catalog will facilitate monitoring of compliance with agency data access policies and assist the agency in maintaining an inventory of datasets as required by the Open Data Executive Order ("Making Open and Machine Readable the New Default for Government Information") and the accompanying memorandum from the Office of Management and Budget ("Open Data Policy - Managing Information as an Asset"). Moreover, it will increase the visibility and impact of

Required Knowledge and Skills of Resident

(identify requirements necessary to successfully complete the project – technical skills, educational background, specialized experience, etc.)

-Coursework in Digital Libraries, Digital Curation, Organization of Information, Metadata, or Cataloging.
-Demonstrated Project Management skills and experience.
-Strong interpersonal and communication abilities; ability to interface with diverse stakeholders including research administrators and scientific staff.
-Ability to quickly understand plain-language summaries to develop descriptive metadata for research products in CDRH disciplines such as: Biomedical Engineering, Biomedical Physics, Biochemistry, Material Science, Applied Mathematics, Computer Science, etc.
-Functional competency in Dublin Core Metadata Initiative standards.
-Working knowledge of digital curation lifecycle, research lifecycle, bibliographic utilities, and catalogue

Preferred Knowledge or Experience of Resident

(identify preferred knowledge or experience – technical skills, educational background, specialized experience, etc.)

-A professional interest in 'non-traditional' Library & Information Science roles and biomedical or STEM information environments.
-A passion for open data/open access.
-Specialized experience or coursework in eScience or Research Data Management.
-Familiarity with Agile Project Management Methodologies.
-Ability to quickly become familiar with CDRH controlled vocabulary